National Cancer Institute

Procedure Description

SUBJECT: Develop and Maintain SOPs for the caBIG™ Program	SOP No.: AD-001
	Version No.: 1.0
	Effective Date: 10/31/2005
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Step	Action
1.	**Author prepares new SOPs and initiates the review process.** A. Follow the approved standardized format for each SOP. B. Present a draft of the SOP to the SOP Working Group for review of proper format, content, appropriate references, and regulations. C. Incorporate any comments into the draft SOP. D. Final approval will be obtained by the SOP Working Group by the 2nd SOP Working Group meeting following the meeting in which the initial draft SOP is presented.
2.	**The Document Officer works with the Author to assign version number and baseline approved SOPs.** A. Approved SOPs are assigned a version number, in accordance with the *Procedure Description for Numbering and Versioning of SOPs*. To determine the scope of the release, the Author and Document Officer will confer with the SOP Working Group Chair or designee. B. The Document Officer will also assign the issue date, the date the SOP/version becomes effective. The issue date will be a sufficient amount of time after posting to allow adequate time for training on the SOP and related procedures.
3.	**The NCICB Applications Director approves SOP.** A. The SOP and all related documents are printed for signature. B. The SOP will be signed by the NCICB Applications Director to indicate NCICB approval for distribution. C. The SOP will then be signed by the appropriate QA representative.
4.	**NCICB QA Officer conducts annual review of approved SOPs.** A. Review each approved SOP annually unless otherwise noted in the SOP.